

REMARKS

Claims 1-20 are all the claims pending in the application; claims 1-12 have been withdrawn from consideration; claims 13-20 have been rejected.

Upon entry of this amendment, claims 1-12 will be canceled, new claims 21-29 will be added, and claims 13-29 will be pending.

New claims 21-29 are fully supported by the specification. Support for claim 21 may be found at paragraph [0176]. Support for claims 22-29 may be found, for example, in Example 7, beginning at page 37 of the specification.

No new matter has been added. Entry of the Amendment is respectfully requested.

I. Information Disclosure Statement

With the Office Action dated August 24, 2005, the Examiner returned copies of the document lists submitted with the Information Disclosure Statements (IDS) in this application on December 19, 2003, and April 4, 2005.

As to the document list submitted April 4, 2005, the Examiner crossed through the Gryglewski et al. and Pereira et al. citations, acknowledging only the Weksler et al. citation. As to the document list submitted December 19, 2003, the Examiner only acknowledged consideration of the Ngo et al. document.

At paragraph 3 of the Office Action, the Examiner states that none of the other references were provided.

Applicants respectfully note that each of the documents cited on the document lists was either provided to the Examiner in one of the parent applications, or cited by the Examiner on a Form PTO 892 during prosecution of one of the parent applications. As set forth in 37

C.F.R. §1.98(d), copies of documents provided in an earlier application do not need to be provided if the earlier application is cited in the IDS. Because the IDS filed in the pending application cited parent application number 10/608,536, which claims benefit of other applications in which the documents were first submitted, the Examiner is respectfully requested to obtain copies of the documents from the parent applications.

Submitted herewith is a supplemental IDS, listing each of the documents that has not yet been acknowledged by the Examiner, as well as one additional document (Hara et al.) cited in parent application number 09/037,758 but mistakenly omitted from the document lists filed with the IDS in the pending application.

Applicants respectfully request return of an initialed and signed copy of the document list, indicating the Examiner's consideration of each listed document.

II. Priority

In paragraph 4 of the Office Action, the Examiner states that Applicants' claim for domestic priority under 35 U.S.C. §119(e) is acknowledged. Applicants respectfully note that a claim for domestic priority under 35 U.S.C. §119(e) (i.e., to a prior filed U.S. provisional application) has not been made in the instant application.

III. Specification

At paragraph 5 of the Office Action, the Examiner notes that the first paragraph of the specification should be updated and corrected with regard to the priority application information.

Included herewith is an amendment to the specification in the manner suggested by the Examiner.

IV. Claim Rejections Under 35 U.S.C. §112

A. At paragraph 7 of the Office Action, claims 13-20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

The Examiner states claims 13 and 17 are indefinite for the following reasons: (i) the phrase “immunological activity” in claim 13 is ambiguous and unclear, and the metes and bounds of the claimed “immunological activity” is not defined; (ii) the term “part” in claim 13 is not defined; (iii) the phrase “substantially depicted” in claim 13, and the term “depicted” in claim 17, are ambiguous and unclear, and the metes and bounds of the claim limitation is not defined; and (iv) the phrase “part...of an amino acid sequence” recited in claim 13 is ambiguous as it may mean “a part of SEQ ID NO:2 as small as two amino acid residues.”

Include herewith is amendment to the claims such that each of the terms and phrases objected to by the Examiner has been canceled from the claims.

In view of the amendment to the claims, the claims are definite as written. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

B. At paragraph 9 of the Office Action, claims 13-20 are rejected under 35 U.S.C. §112, first paragraph, as being non-enabled.

The Examiner states that while the specification is enabling for an antibody that specifically binds to a peptide consisting of SEQ ID NO:18, it does not reasonably provide enablement for any antibody that binds “part” of SEQ ID NO:18 as recited in claim 13, or any antibody that binds a peptide as “substantially depicted” in SEQ ID NO:18.

Included herewith is an amendment to the claims such that the claims do not recite antibodies that bind to a “part” of SEQ ID NO:18 or antibodies that bind to a peptide as “substantially depicted” in SEQ ID NO:18.

In view of the amendment to the claims, the claims are fully enabled. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

C. At paragraph 10 of the Office Action, claims 13-20 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Examiner states that while Applicants are in possession of an antibody that specifically binds to the peptide of SEQ ID NO:18, they are not in possession of any antibody that binds to any polypeptide part, or any antibody that binds to any peptide as substantially depicted in SEQ ID NO:18.

As noted above, included herewith is an amendment to the claims such that the claims do not recite antibodies that bind to a “part” of SEQ ID NO:18 or antibodies that bind to a peptide as “substantially depicted” in SEQ ID NO:18.

In view of the amendment to the claims, the claims have adequate written description support in the specification. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

V. Claim Rejections Under 35 U.S.C. §102

At paragraph 12 of the Office Action, claims 13-15 and 17-19 are rejected under 35 U.S.C. §102(b) as being anticipated by Weksler (1990).

The Examiner states that Weksler teaches a monoclonal antibody to PGI₂ synthase. The Examiner notes that in view of the limitation in claim 13 that the antigen is as “substantially

depicted” in SEQ ID NO:18, the antibodies of the claim are not limited to those that bind SEQ ID NO:18, and the claim would encompass the antibodies of Weksler.

As discussed above, included herewith is an amendment to the claims such that the claims no longer recite an antibody that binds to a peptide as “substantially depicted” in SEQ ID NO:18. As Weksler does not teach an antibody that specifically binds to an epitope consisting of residues 1-12 of SEQ ID NO:18, Weksler does not teach each and every element of the pending claims. Therefore, Weksler does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

VI. Claim Rejections Under 35 U.S.C. §103

At paragraph 14 of the Office Action, claims 13-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Miyata et al. (1994) in view of Campbell (1984).

The Examiner states that Miyata et al. discloses the sequence information of human prostacyclin synthase, but does not teach antibodies raised against the protein. The Examiner cites to Campbell as teaching the advantages of antibodies, their use in diagnosis and treatment, and the customary practice of making antibodies even without a clear objective for their application. The Examiner concludes that one of ordinary skill in the art would have been motivated to make antibodies for the purpose of diagnosis and treatment, with a reasonable expectation of success.

In order for the Examiner to maintain a rejection under 35 U.S.C. §103, the Examiner must show (1) that the cited references teach each and every element of the claim, (2) that there is a suggestion or motivation in the cited references or the general knowledge of the art to

modify the references to make the claimed invention, and (3) that there is a reasonable expectation of success that the modification will yield the claimed subject matter. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See also MPEP §2142.

Applicants respectfully assert that the Examiner has not established a *prima facie* showing of obviousness.

First, the cited art does not teach each and every element of the claimed invention. In particular, there is no teaching in either Miyata or Campbell of an antibody that specifically binds to the peptide of SEQ ID NO:18. That is, neither Miyata or Campbell teaches the particular species of peptide used by Applicants to produced antibodies (the 12 amino acid peptide of SEQ ID NO:18).

Second, there is no suggestion or motivation in either Miyata or Campbell to produce an antibody against the epitope formed by the peptide of SEQ ID NO:18. While Miyata may teach human prostacyclin synthase, no where in this publication is a suggestion or motivation to raise an antibody against the particular epitope of SEQ ID NO:18. *In re Deuel*, 51 F.3d 1552,1557, 34 USPQ2d 1210, 1214 (“[A] *prima facie* case of unpatentability requires that the teachings of the prior art suggest *the claimed compounds* to a person of ordinary skill in the art.” (emphasis in original)); *In re Lahu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984) (“The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound.”).

As stated in MPEP §2144.08(II)(A)(4), examiners must consider a number of factors when determining whether one of ordinary skill in the art would have been motivated to select the claimed species in view of a genus. These factors include the size of the genus. In this

regard, as the full-length polypeptide contains 500 amino acids, there are hundreds of different 12 amino acid peptides that could be derived from the full-length polypeptide. There is nothing in the cited art to suggest or motivate the skilled artisan to select the 12 amino acid peptide of SEQ ID NO:18 for use in the production of antibodies.

Examiners must also consider the express teachings of the art. Applicants note that the Examiner has not identified any teaching of using the peptide of SEQ ID NO:18 as the epitope against which antibodies may be raised. Neither is there any teaching of structurally similar peptides in the art that may be used in the production of antibodies that would motivate one of ordinary skill in the art to choose the peptide of SEQ ID NO:18.

Examiners also need to consider the predictability of the technology. While the skilled artisan may be able to produce antibodies to a given peptide, the binding specificity of the resulting antibody is not predictable for a particular antigen. As discussed in Example 7 (see paragraph 176) of the specification, the antibody raised against the 12 amino acid human peptide of SEQ ID NO:18 is highly specific as it binds human prostacyclin synthase, but does not bind bovine PGIS.

In view of these comments, Applicants respectfully contend that the neither Miyata nor Campbell, alone or in combination, teaches or suggests the claimed invention. Thus, as the Examiner has not established a *prima facie* case of obvious, Applicants request reconsideration and withdrawal of this rejection.

VII. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Appln. No. 10/663,749

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Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.


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